

106TH CONGRESS  
2D SESSION

# H. R. 4395

To amend title XVIII of the Social Security Act to improve the manner in which new medical technologies are made available to Medicare beneficiaries under the Medicare Program, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

MAY 8, 2000

Mr. RAMSTAD (for himself and Mrs. THURMAN) introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committee on Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## A BILL

To amend title XVIII of the Social Security Act to improve the manner in which new medical technologies are made available to Medicare beneficiaries under the Medicare Program, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

### 3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the  
5 “Medicare Access to Technology Act of 2000”.

6 (b) TABLE OF CONTENTS.—The table of contents of  
7 this Act is as follows:

- Sec. 1. Short title; table of contents.
- Sec. 2. Annual reports on national coverage determinations.
- Sec. 3. Improvements to the medicare advisory committee process.
- Sec. 4. Inclusion on MedPAC of an individual with expertise in new medical devices.
- Sec. 5. Annual adjustments to medicare payment systems for changes in technology and medical practice.
- Sec. 6. Annual reports on elimination of barriers to use of new medical devices in hospital outpatient settings.
- Sec. 7. Clarification of standard for coverage of drugs and biologicals.
- Sec. 8. Process for making and implementing HCPCS coding modifications.
- Sec. 9. Retention of HCPCS level III codes.
- Sec. 10. Process for making and implementing ICD-9-CM coding modifications.
- Sec. 11. Establishment of procedures for medicare coding and payment determinations for new clinical diagnostic laboratory tests and other items on a fee schedule.

1 **SEC. 2. ANNUAL REPORTS ON NATIONAL COVERAGE DE-**  
 2 **TERMINATIONS.**

3 (a) ANNUAL REPORTS.—Not later than December 1  
 4 of each year, beginning in 2001, the Secretary of Health  
 5 and Human Services shall submit to Congress a report  
 6 that sets forth a detailed compilation of the actual time  
 7 periods that were necessary to complete and fully imple-  
 8 ment any national coverage determinations that were  
 9 made in the previous fiscal year for items, services, or  
 10 medical devices not previously covered as a benefit under  
 11 title XVIII of the Social Security Act (42 U.S.C. 1395  
 12 et seq.), including, with respect to each new item, service,  
 13 or medical device, a statement of the time taken by the  
 14 Secretary to make the necessary coverage, coding, and  
 15 payment determinations, including the time taken to com-  
 16 plete each significant step in the process of making such  
 17 determinations.

1 (b) PUBLICATION OF REPORTS ON THE INTERNET.—  
2 The Secretary of Health and Human Services shall pub-  
3 lish each report submitted under subsection (a) on the  
4 medicare Internet site of the Department of Health and  
5 Human Services.

6 **SEC. 3. IMPROVEMENTS TO THE MEDICARE ADVISORY**  
7 **COMMITTEE PROCESS.**

8 Section 1114 of the Social Security Act (42 U.S.C.  
9 1314) is amended by adding at the end the following new  
10 subsection:

11 “(i)(1) Any advisory committee appointed under sub-  
12 section (f) to advise the Secretary on matters relating to  
13 the interpretation, application, or implementation of sec-  
14 tion 1862(a)(1) shall assure the full participation of a  
15 nonvoting member in the deliberations of the advisory  
16 committee, and shall provide such nonvoting member ac-  
17 cess to all information and data made available to voting  
18 members of the advisory committee, other than informa-  
19 tion that—

20 “(A) is exempt from disclosure pursuant to sub-  
21 section (a) of section 552 of title 5, United States  
22 Code, by reason of subsection (b)(4) of such section  
23 (relating to trade secrets); and

1           “(B) the Secretary determines would present a  
2           conflict of interest relating to such nonvoting mem-  
3           ber.

4           “(2) If an advisory committee described in paragraph  
5 (1) organizes into panels of experts according to types of  
6 items or services considered by the advisory committee,  
7 any such panel of experts may report any recommendation  
8 with respect to such items or services directly to the Sec-  
9 retary without the prior approval of the advisory com-  
10 mittee or an executive committee thereof.”.

11 **SEC. 4. INCLUSION ON MEDPAC OF AN INDIVIDUAL WITH**  
12 **EXPERTISE IN NEW MEDICAL DEVICES.**

13           (a) IN GENERAL.—Section 1805(c)(2)(B) of the So-  
14 cial Security Act (42 U.S.C. 1395b–6(c)(2)(B)) is amend-  
15 ed by inserting “individuals with national recognition for  
16 their expertise in the development for market of new med-  
17 ical items, services, and devices,” after “other health pro-  
18 fessionals,”.

19           (b) EFFECTIVE DATE.—The amendment made by  
20 subsection (a) applies with respect to members appointed  
21 to the Medicare Payment Advisory Commission on or after  
22 the date of the enactment of this Act.

1 **SEC. 5. ANNUAL ADJUSTMENTS TO MEDICARE PAYMENT**  
2 **SYSTEMS FOR CHANGES IN TECHNOLOGY**  
3 **AND MEDICAL PRACTICE.**

4 (a) IN GENERAL.—Title XVIII of the Social Security  
5 Act (42 U.S.C. 1395 et seq.) is amended by inserting after  
6 section 1888 the following new section:

7 “ANNUAL ADJUSTMENTS TO MEDICARE PAYMENT SYS-  
8 TEMS FOR CHANGES IN TECHNOLOGY AND MEDICAL  
9 PRACTICE

10 “SEC. 1889. (a) IN GENERAL.—

11 “(1) ASC, MFS, AND INPATIENT PPS.—Not-  
12 withstanding any other provision of this title, the  
13 Secretary shall adjust the appropriate elements of  
14 the payment systems established under sections  
15 1833(i)(2)(A), 1848, and 1886(d) (including relative  
16 payment weights, relative value units, weighting fac-  
17 tors, diagnosis-related group classifications, and as-  
18 signments to diagnosis-related groups) at least an-  
19 nually to ensure that payments under such systems  
20 appropriately reflect changes in medical technology  
21 and medical practice affecting the items and services  
22 for which payment may be made under such sys-  
23 tems.

24 “(2) OP PPS.—For a provision requiring ad-  
25 justments to the elements of the outpatient prospec-

1        tive payment system at least annually, see section  
2        1833(t)(9)(A).

3        “(b) RULES FOR DETERMINING ADJUSTMENTS.—

4        Except as provided in subsection (c), the provisions of sec-  
5        tion 1833(i)(2)(A), section 1848(c)(2)(B), and section  
6        1886(d)(4)(C) shall apply to the annual adjustments re-  
7        quired by this section in the same manner and to the same  
8        extent as they apply to the periodic adjustments of relative  
9        payment weights, relative value units, weighting factors,  
10       diagnosis-related group classifications, and assignments to  
11       diagnosis-related groups, respectively, that are authorized  
12       or required by such sections.

13       “(c) USE OF INTERNAL DATA COLLECTED BY THE  
14       SECRETARY.—

15                “(1) IN GENERAL.—In determining the adjust-  
16       ments required by this section and section  
17       1833(t)(9)(A), the Secretary may not—

18                “(A) decline to make an adjustment that is  
19       based on data collected by the Secretary in the  
20       administration of the program established  
21       under this title if the data reflect a representa-  
22       tive sample of cases that is statistically valid;  
23       and

1           “(B) establish a uniform period of time  
2           (such as one year) from which such data must  
3           be drawn.

4           “(2) DEADLINE FOR SUPPLYING INTERNAL  
5           DATA.—The Secretary shall establish a reasonable  
6           deadline for the submission of data collected by the  
7           Secretary to be used in making the adjustments re-  
8           quired by this section or section 1833(t)(9)(A). In  
9           no event may the deadline established under this  
10          paragraph be more than seven months before the  
11          first day of the provider payment update period for  
12          which the adjustment or adjustments to which the  
13          data relate would be effective.

14          “(d) USE OF EXTERNAL DATA.—

15                 “(1) IN GENERAL.—Subject to paragraph (2),  
16                 in determining the adjustments required by this sec-  
17                 tion and section 1833(t)(9)(A), the Secretary shall  
18                 utilize data other than data collected by the Sec-  
19                 retary in the administration of the program estab-  
20                 lished under this title if—

21                         “(A) data collected by the Secretary in the  
22                         administration of such program are not avail-  
23                         able at the time such adjustments are being de-  
24                         termined; and

1           “(B) such other data are reliable and  
2           verifiable.

3           “(2) EXTERNAL DATA FACILITATING THE USE  
4           OF INTERNAL DATA.—

5           “(A) IN GENERAL.—In determining the  
6           adjustments required by this section and section  
7           1833(t)(9)(A), the Secretary may not—

8                   “(i) decline to use data other than  
9                   data collected by the Secretary if such  
10                  other data—

11                          “(I) enable the Secretary to iden-  
12                          tify or refine data collected by the  
13                          Secretary for use in making such an  
14                          adjustment; and

15                          “(II) are based on a representa-  
16                          tive sample of cases that is statis-  
17                          tically valid; or

18                          “(ii) establish a uniform period of  
19                          time (such as one year) from which such  
20                          data must be drawn.

21           “(B) SPECIAL RULE.—

22                          “(i) WAIVER OF REQUIREMENT FOR  
23                          INDIVIDUAL AUTHORIZATION FOR DISCLO-  
24                          SURE OF PROTECTED HEALTH INFORMA-  
25                          TION.—Notwithstanding any other provi-



1 sion of law, individual authorization is not  
2 required for disclosure of protected health  
3 information to—

4 “(I) a government agency or pri-  
5 vate payer; or

6 “(II) a private entity for the pur-  
7 pose of disclosure to such an agency  
8 or payer,

9 for inclusion in data systems of the agency  
10 or payer for use in the formulation of cov-  
11 erage, coding, and payment policies of the  
12 agency or payer.

13 “(ii) CONSTRUCTION.—Nothing in  
14 clause (i) shall be construed as authorizing  
15 the disclosure or use of such information  
16 by such an agency, payer, or entity for any  
17 other purpose.

18 “(3) ALTERNATIVE SOURCES OF DATA.—In de-  
19 termining the adjustments required by this section  
20 and section 1833(t)(9)(A), the Secretary shall use  
21 data, that otherwise meet the requirements of this  
22 subsection, collected by (or on behalf of)—

23 “(A) private payers;

24 “(B) manufacturers of medical tech-  
25 nologies;

1 “(C) suppliers;

2 “(D) groups representing physicians and  
3 other health care professionals;

4 “(E) groups representing providers;

5 “(F) clinical trials; and

6 “(G) such other sources as the Secretary  
7 determines to be appropriate.

8 “(4) CLARIFICATION.—Nothing in this title  
9 shall be construed as—

10 “(A) requiring the Secretary to identify all  
11 claims submitted under a payment system es-  
12 tablished under section 1833(i)(2)(A), section  
13 1833(t), section 1848, or section 1886(d) in-  
14 volving the use of a medical technology before  
15 the Secretary may make the adjustments under  
16 this section (or under section 1833(i)(2)(A),  
17 section 1833(t), section 1848, or section  
18 1886(d)) with respect to such technology; or

19 “(B) authorizing the Secretary to defer ac-  
20 tion on such an adjustment until all such claims  
21 are identifiable.

22 “(5) DEADLINE FOR SUPPLYING EXTERNAL  
23 DATA.—The Secretary shall establish a reasonable  
24 deadline for the submission of data other than data  
25 collected by the Secretary to be used in making the

1 adjustments required by this section or section  
2 1833(t)(9)(A). In no event may the deadline estab-  
3 lished under this paragraph be more than 9 months  
4 before the first day of the provider payment update  
5 period for which the adjustment or adjustments to  
6 which the data relate would be effective.

7 “(e) TIMING OF ADJUSTMENTS.—

8 “(1) IN GENERAL.—The annual adjustments  
9 required by this section shall—

10 “(A) apply to provider payment update pe-  
11 riods beginning on or after October 1, 2001;  
12 and

13 “(B) be described in the proposed and  
14 final rules published by the Secretary with re-  
15 spect to changes to a payment system estab-  
16 lished under section 1833(i)(2)(A), 1848, or  
17 1886(d) for the provider payment update period  
18 to which they relate, together with a description  
19 of the data on which such adjustments are  
20 based.

21 “(2) DEFINITION.—For purposes of this sec-  
22 tion, the term ‘provider payment update period’  
23 means—

1           “(A) in the case of the payment system es-  
 2           tablished under section 1833(i)(2)(A) or section  
 3           1848, a calendar year; and

4           “(B) in the case of the payment system es-  
 5           tablished under section 1886(d), a fiscal year  
 6           beginning on October 1.”.

7           (b) CONFORMING AMENDMENTS.—

8           (1) AMBULATORY SURGICAL CENTERS.—Section  
 9           1833(i)(2)(A) of the Social Security Act (42 U.S.C.  
 10          1395l(i)(2)(A)) is amended by striking “Each” in  
 11          the second sentence thereof and inserting “Subject  
 12          to section 1889, each”.

13          (2)           PHYSICIAN           PAYMENT.—Section  
 14          1848(c)(2)(B)(i) of such Act (42 U.S.C. 1395w-  
 15          4(c)(2)(B)(i)) is amended by striking “The” and in-  
 16          serting “Subject to section 1889, the”.

17          (3) INPATIENT HOSPITAL PROSPECTIVE PAY-  
 18          MENT SYSTEM.—Section 1886(d)(4)(C)(i) of such  
 19          Act (42 U.S.C. 1395ww(d)(4)(C)(i)) is amended by  
 20          striking “The” and inserting “Subject to section  
 21          1889, the”.

1 **SEC. 6. ANNUAL REPORTS ON ELIMINATION OF BARRIERS**  
2 **TO USE OF NEW MEDICAL DEVICES IN HOS-**  
3 **PITAL OUTPATIENT SETTINGS.**

4 (a) REPORT BY SECRETARY ON ACCESS TO DE-  
5 VICES.—Section 1833(t)(13) of the Social Security Act  
6 (42 U.S.C. 1395l(t)(13)) is amended by adding at the end  
7 the following new subparagraph:

8 “(B) REPORT ON ACCESS TO DEVICES.—  
9 Not later than December 1 of each year begin-  
10 ning with 2001, the Secretary shall submit to  
11 Congress a report on access of individuals fur-  
12 nished covered OPD services (as defined in  
13 paragraph (1)(B)) to medical devices in con-  
14 junction with such services. Such report shall  
15 include an analysis of the impact of paragraph  
16 (6)(A) in making new devices available in hos-  
17 pital outpatient departments, the extent to  
18 which barriers to such availability have been  
19 overcome by reason of such paragraph, the im-  
20 pact of including or excluding a device under  
21 the payment system established by this sub-  
22 section on beneficiary access to such device, and  
23 a description of efforts by the Secretary to in-  
24 crease the use and availability of such devices  
25 in such departments. For purposes of this sub-  
26 paragraph, the term ‘device’ means any item

1           that is treated as a device under section 201(h)  
2           of the Federal Food, Drug, and Cosmetic Act.”.

3           (b) MEDPAC REPORT ON NEW DEVICES.—Section  
4 1805(b)(2)(C) of the Social Security Act (42 U.S.C.  
5 1395b–6(b)(2)(C)) is amended by adding at the end the  
6 following: “In conducting such review, the Commission  
7 shall monitor medicare beneficiary access to medical de-  
8 vices for which payment is made under section 1833(t)  
9 in hospital outpatient departments, shall assess the impact  
10 of paragraph (6)(A) of such section in making new devices  
11 available in such departments, the extent to which barriers  
12 to such availability have been overcome by reason of such  
13 paragraph, and the impact of including or excluding a de-  
14 vice under the payment system established by section  
15 1833(t) on beneficiary access to such device, and shall  
16 make any recommendations the Commission determines  
17 would increase availability of such devices to individuals  
18 entitled to benefits under this title. For purposes of this  
19 subparagraph, the term ‘device’ means any item that is  
20 treated as a device under section 201(h) of the Federal  
21 Food, Drug, and Cosmetic Act.”.

22 **SEC. 7. CLARIFICATION OF STANDARD FOR COVERAGE OF**  
23 **DRUGS AND BIOLOGICALS.**

24           (a) IN GENERAL.—Section 1862(a) of the Social Se-  
25 curity Act (42 U.S.C. 1395y(a)) is amended by adding at

1 the end the following: “A drug or biological may not be  
 2 excluded from coverage under this title by reason of para-  
 3 graph (1)(A) if the drug or biological has been approved  
 4 by the Food and Drug Administration and is prescribed  
 5 for a use that has been approved by the Food and Drug  
 6 Administration or that is supported by one or more cita-  
 7 tions that are included (or approved for inclusion) in one  
 8 or more of the compendia referred to in section  
 9 1861(t)(2)(B)(ii)(I).”.

10 (b) EFFECTIVE DATE.—The amendment made by  
 11 subsection (a) shall apply to coverage determinations  
 12 made on or after the date of enactment of this Act.

13 **SEC. 8. PROCESS FOR MAKING AND IMPLEMENTING HCPCS**

14 **CODING MODIFICATIONS.**

15 (a) IN GENERAL.—Notwithstanding any other provi-  
 16 sion of title XVIII of the Social Security Act (42 U.S.C.  
 17 1395 et seq.), the Secretary of Health and Human Serv-  
 18 ices shall—

- 19 (1) not later than 30 days after the receipt of  
 20 a written request of a product sponsor, assign a  
 21 temporary code to a drug or device reviewed by the  
 22 Food and Drug Administration;
- 23 (2) accept recommendations for HCPCS level II  
 24 code modifications from the public throughout the  
 25 year;

1           (3) cause determinations on such recommenda-  
2           tions to be made within 30 days after receipt of the  
3           recommendation; and

4           (4) incorporate modifications to HCPCS level II  
5           codes that are approved during the 3 months pre-  
6           ceding the last month of a calendar quarter into the  
7           payment systems established under such title (in-  
8           cluding the medicare fee schedule data base) not  
9           later than the first day of the following calendar  
10          quarter.

11         (b) ELIMINATION OF REQUIREMENT FOR MAR-  
12         KETING EXPERIENCE.—Notwithstanding any other provi-  
13         sion of title XVIII of the Social Security Act, the Sec-  
14         retary of Health and Human Services may not require a  
15         minimum period of marketing experience with respect to  
16         a drug or device as a condition of consideration or ap-  
17         proval of a recommendation for an HCPCS level II modi-  
18         fication for such drug or device.

19         (c) DEFINITION.—For purposes of this section, the  
20         term “HCPCS level II code modification” means any  
21         change to the alphanumeric codes for items not included  
22         in level I or level III of the Health Care Financing Admin-  
23         istration Common Procedure Coding System (HCPCS).

24         (d) REPORT.—Not later than 180 days after the date  
25         of the enactment of this Act, the Secretary of Health and



1 Human Services shall submit to Congress a report on the  
 2 feasibility and desirability of opening meetings of the  
 3 Alpha-Numeric Editorial Panel of the Department of  
 4 Health and Human Services to the public. If the Secretary  
 5 determines that opening such meetings to the public is not  
 6 feasible or desirable, the Secretary shall include in the re-  
 7 port a detailed explanation of the reasons for such deter-  
 8 mination.

9 (e) EFFECTIVE DATE.—The provisions of this section  
 10 take effect on January 1, 2001.

11 **SEC. 9. RETENTION OF HCPCS LEVEL III CODES.**

12 (a) IN GENERAL.—The Secretary of Health and  
 13 Human Services shall maintain and continue the use of  
 14 level III codes of the HCPCS coding system (as such sys-  
 15 tem was in effect on June 1, 1999), and shall make such  
 16 codes available to the public.

17 (b) DEFINITION.—For purposes of this section, the  
 18 term “HCPCS Level III codes” means the alphanumeric  
 19 codes for local use under the Health Care Financing Ad-  
 20 ministration Common Procedure Coding System  
 21 (HCPCS).

22 **SEC. 10. PROCESS FOR MAKING AND IMPLEMENTING ICD-**  
 23 **9-CM CODING MODIFICATIONS.**

24 (a) IN GENERAL.—Notwithstanding any other provi-  
 25 sion of title XVIII of the Social Security Act (42 U.S.C.

1 1395 et seq.), with respect to payments for inpatient hos-  
2 pital services under section 1886 of such Act (42 U.S.C.  
3 1395ww), the Secretary of Health and Human Services  
4 shall—

5 (1) not later than 30 days after the receipt of  
6 a written request of a product sponsor, assign a  
7 temporary code to a drug or device reviewed by the  
8 Food and Drug Administration;

9 (2) accept recommendations for ICD-9-CM  
10 code modifications from the public throughout the  
11 year;

12 (3) cause determinations on such recommenda-  
13 tions to be made within 30 days after receipt of the  
14 recommendation; and

15 (4) incorporate modifications to ICD-9-CM  
16 codes that are approved during the 3 months pre-  
17 ceding the last month of a calendar quarter into the  
18 payment systems established under such title (in-  
19 cluding the medicare fee schedule data base) not  
20 later than the first day of the following calendar  
21 quarter.

22 (b) ELIMINATION OF REQUIREMENT FOR MAR-  
23 KETING EXPERIENCE.—Notwithstanding any other provi-  
24 sion of title XVIII of the Social Security Act, the Sec-  
25 retary of Health and Human Services may not require a

1 minimum period of marketing experience with respect to  
2 an item, service, or device for which payment is made  
3 under such section 1886 as a condition of consideration  
4 or approval of a recommendation for an ICD–9–CM modi-  
5 fication for such item, service, or device.

6 (c) DEFINITION.—For purposes of this section, the  
7 term “ICD–9–CM code modification” means any change  
8 to the alphanumeric codes of the International Classifica-  
9 tion of Diseases, 9th Revision, Clinical Modification, ap-  
10 plied under such section 1886.

11 (d) MEDPAC REPORT.—Not later than January 1,  
12 2001, the Medicare Payment Advisory Commission estab-  
13 lished under section 1805 of the Social Security Act (42  
14 U.S.C. 1395b–6) shall submit to Congress a report on—

15 (1) the procedures used by the Health Care Fi-  
16 nancing Administration to makes changes to the  
17 classification system, diagnosis-related groups, and  
18 weighting factors established under paragraph (4) of  
19 section 1886(d) of such Act (42 U.S.C. 1395ww(d))  
20 to incorporate new technologies and respond to  
21 changes in technology;

22 (2) whether such procedures ensure that the  
23 payments made under the prospective payment sys-  
24 tem established under such section are appropriate  
25 and timely for new technologies and provide appro-

1        appropriate and timely recognition of changes in the tech-  
 2        nology; and

3            (3) recommendations for such legislation and  
 4        administrative actions as the Commission considers  
 5        appropriate to promote the appropriate and timely  
 6        incorporation of new technologies and the recogni-  
 7        tion of changes in technology under such system.

8    **SEC. 11. ESTABLISHMENT OF PROCEDURES FOR MEDICARE**  
 9                            **CODING AND PAYMENT DETERMINATIONS**  
 10                           **FOR NEW CLINICAL DIAGNOSTIC LABORA-**  
 11                           **TORY TESTS AND OTHER ITEMS ON A FEE**  
 12                           **SCHEDULE.**

13        (a) IN GENERAL.—Not later than one year after the  
 14        date of the enactment of this Act, the Secretary of Health  
 15        and Human Services shall establish procedures for coding  
 16        and payment determinations for the following categories  
 17        of items and services under part B of the title XVIII of  
 18        the Social Security Act (42 U.S.C. 1395 et seq.): new clin-  
 19        ical diagnostic laboratory tests and durable medical equip-  
 20        ment. Such procedures (which may vary for the 2 cat-  
 21        egories of items and services referred to in the preceding  
 22        sentence) shall provide for the following:

23            (1) Such procedures shall be clearly under-  
 24        standable and follow a predictable format. Any hear-  
 25        ings or meetings with respect to the determinations

1 shall be open to the public and provide for public  
2 participation.

3 (2) Under the procedures, the Secretary shall  
4 identify the rules and assumptions to be applied in  
5 considering the coding or payment determination,  
6 and shall provide the sources and types of data to  
7 be used in making such determination.

8 (3) Under the procedures, the Secretary shall  
9 provide a clear statement of the basis for the deter-  
10 mination.

11 (4) Under the procedures, the Secretary shall  
12 make available to the public the data (other than  
13 proprietary data) considered in making the deter-  
14 mination.

15 (5) Under the procedures, the Secretary shall  
16 consider and implement coding modifications under  
17 procedures similar to those for HCPCS level II and  
18 ICD-9-CM procedure and related codes.

19 (6) Under the procedures, the Secretary shall  
20 provide for consistent instructions to carriers to  
21 carry out their functions in setting prices for new  
22 technologies that—

23 (A) are designed to establish fair and ap-  
24 propriate payment levels reflecting market con-  
25 ditions for such items and services; and

1 (B) in the case of clinical diagnostic lab-  
2 oratory tests for which payment is made on a  
3 fee schedule basis under title XVIII of the So-  
4 cial Security Act, comply with the requirements  
5 of section 1833(h)(8) of such Act (42 U.S.C.  
6 1395l(h)(8)).

7 (7) Under the procedures, the Secretary shall  
8 provide a mechanism under which an interested  
9 party may request a timely review of the adequacy  
10 of the existing fee for a particular item or service,  
11 and upon receipt of such a request that such timely  
12 review is carried out.

13 (8) Under the procedures, the Secretary shall  
14 provide for a mechanism under which an interested  
15 party may request administrative review of an ad-  
16 verse coding or payment policy determination, and  
17 shall provide for such review and, if necessary, revi-  
18 sion of the determination.

19 (b) ESTABLISHING PAYMENT RATES FOR NEW LAB  
20 TESTS.—Section 1833(h) of the Social Security Act (42  
21 U.S.C. 1395l(h)) is amended by adding at the end the fol-  
22 lowing:

23 “(8)(A) Notwithstanding paragraphs (1), (2), and  
24 (4), in the case of a clinical diagnostic laboratory test with  
25 respect to which a code is first assigned under the Health

1 Care Financing Administration Common Procedure Cod-  
2 ing System (hereinafter referred to as ‘HCPCS’) on or  
3 after January 1, 2001, the Secretary shall provide for the  
4 establishment of payment rates in accordance with sub-  
5 paragraph (B) or (C).

6 “(B) In the case of a clinical diagnostic laboratory  
7 test described in subparagraph (A) with respect to which  
8 the Secretary proposes to base payment on the fee sched-  
9 ule amounts determined under paragraph (1) and the na-  
10 tional limitation amount determined under paragraph (4)  
11 for one or more similar clinical diagnostic laboratory tests,  
12 the Secretary shall—

13 “(i) cause to have published in the Federal  
14 Register not later than July 1 of each calendar year  
15 (beginning with calendar year 2001) the Secretary’s  
16 proposal with respect to the appropriate fee schedule  
17 amounts and national limitation amount for such  
18 test for the following calendar year; and

19 “(ii) provide an opportunity for the public to  
20 comment on such proposal.

21 “(C)(i) In the case of a clinical diagnostic laboratory  
22 test described in subparagraph (A) with respect to which  
23 payment is not determined in accordance with subpara-  
24 graph (B)—

1           “(I) payment under this subsection shall be  
2       made on the basis of the prevailing charge level for  
3       the test for a locality or area (determined without  
4       regard to the percentage limitation or the base year  
5       referred to in paragraph (2)(A)); and

6           “(II) the limitation amounts referred to in sub-  
7       section (a)(1)(D)(i), subsection (a)(2)(D)(i), and  
8       paragraph (4)(B) shall not apply,  
9       until the beginning of the third full calendar year that be-  
10      gins on or after the date on which an HCPCS code is  
11      first assigned with respect to such test, or, if later, the  
12      beginning of the first calendar year that begins on or after  
13      the date on which the Secretary determines that there are  
14      sufficient claims data to establish a limitation amount  
15      under paragraph (4)(B).

16       “(ii) Notwithstanding paragraph (2)(A), the Sec-  
17      retary shall—

18           “(I) set the fee schedules under paragraph (1)  
19       for a clinical diagnostic laboratory test described in  
20       clause (i) for any calendar year beginning after the  
21       base year at 100 percent of the prevailing charge  
22       level for such test for the applicable region, State,  
23       or area for the base year, adjusted annually (to be-  
24       come effective on January 1 of each year) by the  
25       percentage increase or decrease in the Consumer



1 Price Index for All Urban Consumers (United States  
2 city average), and subject to such other adjustments  
3 as the Secretary determines are justified by techno-  
4 logical changes; and

5 “(II) determine the limitation amount referred  
6 to in subsection (a)(1)(D)(i), subsection (a)(2)(D)(i),  
7 and paragraph (4)(B) for such test based on the fee  
8 schedules set under subclause (I).

9 “(iii) For purposes of clause (ii), the term ‘base year’  
10 means, with respect to a clinical diagnostic laboratory test,  
11 the last full calendar year during which payment for such  
12 test was determined in accordance with clause (i).”.

13 (c) PROHIBITION.—The Secretary may not assign a  
14 code for a new clinical diagnostic laboratory test that dif-  
15 fers from the code recommended by the American Medical  
16 Association Common Procedure Terminology Editorial  
17 Panel and results in lower payment than would be made  
18 if the Secretary accepted such recommendation solely on  
19 the basis that the test is a test that may be performed  
20 by a laboratory with a certificate of waiver under section  
21 353(d)(2) of the Public Health Service Act (42 U.S.C.  
22 263a(d)(2)).

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